

Claims 47-55 have also been rejected under 35 U.S.C § 112, second paragraph.

Applicants contend that the transitional phrase "consisting essentially of" is not confusing and indefinite and is in fact acceptable in form. A further discussion of the scope of this type of claim language will be provided below in the response to the hereinafter described substantive rejections.

Claims 1-24, 36-55, 74, and 76-99 have been rejected under the judicially created doctrine of obviousness-type double patenting. A Terminal Disclaimer is provided herewith to overcome this rejection regarding any claims issuing in this application with respect to U.S. Patent No. 5,989,244.

Claims 49-52 have been indicated by the Examiner to be allowable if amended in the manner provided above. Claims 49 and 51 have been rewritten in independent form as new independent claims 101 and 103. Claims 50 and 52 have been added rewritten as new claims 101 and 104 which are dependent from claims 101 and 103, respectively.

Claims 1-24, 36-55, 74, and 76-99 have been rejected under 35 U.S.C. § 102(a) as being anticipated by Gregory et al, or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Gregory et al in view of Labroo et al.

In order to have anticipation under 35 USC Section 102 (b), every element of the claim must be found in the prior art reference. As stated above, Gregory et al is not a valid reference.

Applicants have previously amended this application to provide that it is a continuation-in-part of U.S. Serial No. 08/341,881, filed November 15, 1994 ("USSN '881"), and a continuation-in-part of USSN 08/658,855 filed on May 31, 1996 ("USSN '855"). USSN '881 is the parent application of the Gregory et al reference cited by the Examiner. A Declaration of

Prior Invention in the United States to Overcome a Cited Publication under 37 C.F.R. 1.131 has been previously presented to the Examiner. In that Declaration it is established that the invention of the pending claims was made at least by a date earlier than the effective date of the Gregory et al reference. The parties making the Declaration are Dr. Kenton Gregory and Mr. Andrew Barofsky, the co-inventors of the above referenced application. Dr. Gregory is also one of the co-inventors of the PCT publication which is in fact the Gregory et al reference. This Declaration overcomes the Gregory et al reference and renders moot all rejections based thereon. Accordingly, it is Applicant's view that Gregory et al cannot be cited as a prior art reference against this application, particularly either under 35 U.S.C. § 102(a) or under 35 U.S.C. § 103(a). Additional information regarding the issue of diligence will be provided to the Examiner under separate cover.

Applicants have amended the claims pending in this application to recite that the biomaterial is consisting essentially of tropoelastin. Section 2111.3 of the MPEP states that this transitional phase limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristics of the claimed invention. Applicants believe that fibrin and other such monomers, such as the polypeptides of the Labroo reference, do not fall within the definition of consisting essentially of tropoelastin.

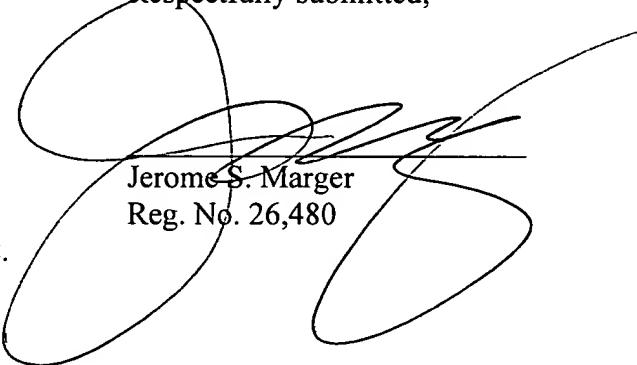
Claims 47 and 48 have been rejected under 35 U.S.C. § 102 (b) as being anticipated by Bedell-Hogan et al. In order to have anticipation under 35 USC Section 102 (b), every element of the claim must be found in the prior art reference. Claims 47 and 48 include the step of forming a biomaterial from the polymer consisting essentially of tropoelastin. This is not described in the Bedell-Hogan et al reference. Therefore, the above rejection does not constitute prima facie anticipation under 35 U.S.C. § 102 (b).

Claims 36-46 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Schwartz et al. In claims 36-46, Applicants have added the language that the biomaterial employed is "consisting essentially of" tropoelastin. In order to have anticipation under 35 U.S.C. § 102(b), each and every element of the claim must be found in the prior art reference. Schwartz et al does not disclose, suggest or teach a biomaterial consisting essentially of tropoelastin. Schwartz et al disclose the use of the crosslinking fibrin material described in the Rabaud et al reference. Rabaud et al. does not relate to the use or production of an elastin or tropoelastin composition except when fibrin is a major essential component of that composition. Fibrin is included in the composition disclosed in Rabaud et al. because it has been determined that fibrin is necessary to crosslink or polymerize the elastin to produce a structural matrix. Therefore, the requirements for a *prima facie* case of anticipation have not been met with respect to the rejection of claims 36-46 as being anticipated by the Schwartz et al reference.

Claims 47, 48, and 53-55 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Labroo et al. In claims 47, 48, and 53-55, Applicants have added the language that the biomaterial employed is "consisting essentially of" tropoelastin. In order to have anticipation under 35 U.S.C. § 102(b), each and every element of the claim must be found in the prior art reference. Labroo et al relates to polypeptide materials. It does not disclose, suggest or teach a biomaterial consisting essentially of tropoelastin. Therefore, the requirements for a *prima facie* case of anticipation have not been met with respect to the rejection of claims 47, 48, and 53-55 as being anticipated by the Labroo et al reference.

In light of the above arguments and amendments to the claims, it is requested that the Examiner reconsider his rejections and pass this case to issue. If, however, the Examiner still believes that has not responded to all of the rejections presently outstanding, he is encouraged to call the Attorney for the Applicants at the telephone number below to discuss same.

Respectfully submitted,



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